PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)* see form PCT/ISA/210 (second sheet)	
Applicant's or agent's file reference see form PCT/ISA/220	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IB2004/000821	19.03.2004	21.03.2003

International Patent Classification (IPC) or both national classification and IPC
A61K9/20

Applicant
RANBAXY LABORATORIES LIMITED

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:	Authorized Officer
European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	VON EGGELKRAUT, S Telephone No. +31 70 340-4732

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IB2004/000821

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was field, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☐ in written format

   ☐ in computer readable form

   c. time of filing/furnishing:

   ☐ contained in the international application as filed.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. II Priority

1. ☒ The following document has not been furnished:

   ☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

   ☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

   Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IB2004/000821

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 49 and 50 with respect to industrial applicability

because:

☒ the said international application, or the said claims Nos. 49 and 50 with respect to industrial applicability relate to the following subject matter which does not require an international preliminary examination *(specify)*:

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the whole application or for said claims Nos.

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form ☐ has not been furnished

☐ does not comply with the standard

the computer readable form ☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	7,11,12,14-28,35-37,42-48,50
	No:	Claims	1-6,8-10,13,29-34,38-41,49
Inventive step (IS)	Yes:	Claims	24, 27, 47
	No:	Claims	1-23, 25,26,28-46,48-50
Industrial applicability (IA)	Yes:	Claims	1-48
	No:	Claims	

2. Citations and explanations

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

III. Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1

1.1 Claims 49 and 50 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

V. Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

For the assessment of the present claims 49 and 50 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

2 Reference is made to the following documents:

D1 : US 6 031 004 A (BRETNALL ALISON E ET AL) 29 February 2000 (2000-02-29)

D2 : WO 01/39749 A (JAIN RAJESH ; SINGH AMARJIT (IN); PANACEA BIOTEC LTD (IN)) 7 June 2001 (2001-06-07)

D3 : EP 1 004 304 A (SUMITOMO PHARMA) 31 May 2000 (2000-05-31)

D4: ROTE LISTE SERVICE GMBH (ED): "Rote Liste 2002" 2002, ROTE LISTE 2002. ARZNEIMITTELVERZEICHNIS FUER DEUTSCHLAND (EINSCHLIESLICH EU - ZULASSUNGEN UND BESTIMMTER MEDIZINPRODUKTE), AULENDORF : EDITIO CANTOR, DE,GLUCOPHAGE (12054) , XP002287756 ISBN: 3-87193-252-3

3 INDEPENDENT CLAIMS 1, 29 and 49

3.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1, 29 and 49 is not new in the sense of Article 33(2) PCT.

3.2 Document D1 discloses (the references in parenthesis applying to this document): Tablets comprising metformin succinate, xylitol and flavours (examples 9 and 10). The disclosure of document D1 falls within the scope of protection sought for tablets comprising a salt of metformin, at least one sugar alcohol and at least one additional water-soluble excipient. The term water-soluble is broadly construed. No experimental conditions are given that would enable the skilled person to verify whether a tablet falls within the scope of the claims or not. The tablets disclosed in D1 are therefore considered to fall within the scope of claims 1,29 and 49, for they comprise the water-soluble excipients as claimed.

4 DEPENDENT CLAIMS 2-23, 25, 26, 28, 30-46, 48, 50

4.1 Dependent claims 2-23, 25, 26, 28, 30-46, 48, 50 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT).

4.2 Document D2 discloses (the references in parenthesis applying to this document): Fast dissolving tablets comprising cetirizine dihydrochloride, mannitol, polyvinylpyrrolidone, aspartame and sodium chloride (example 5). The description discloses that the invention is useful for the formulation of a range of different drugs and their salts, including metformin (page 3, paragraph 3 - page 4, last line).

4.3 Document D3 discloses (the references in parenthesis applying to this document): Tablets comprising metformin, ascorbic acid, mannitol, HPMC (hydroxypropylmethylcellulose) (paragraph 71). The compositions may also comprise xylitol (claim 7).

4.4 Tablets comprising polyethylene glycol and metformin salt are known from

documents D4, namely from the commercial product Glucophage ®.

5 DEPENDENT CLAIMS 24, 27, 47

5.1 The combination of the features of dependent claims 24, 27, 47 is neither known from, nor rendered obvious by, the available prior art. The reasons are as follows: Neither of documents D1 to D4 discloses or suggests water-soluble tablets comprising a salt of metformin and sodium propionate, nor are water-soluble tablets comprising a salt of metformin, micronized polyethylene glycol, xylitol and spray-dried mannitol disclosed.

VIII. Re Item VIII
Certain observations on the international application

6 The application does not meet the requirements of Article 6 PCT, because claims 1-5, 8, 18-23, 27, 29-33, 39, 44, 45, 47 and 49 are not clear.

6.1 Claims 1-5, 29-31 do not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The claims attempt to define the subject-matter in terms of the result to be achieved, which merely amounts to a statement of the underlying problem, without providing the technical features necessary for achieving this result. Said the technical teaching of said claims does not enable the skilled person to arrive at a tablet having the claimed properties without undue burden. Furthermore, the claims lack indication of the temperature under which the testing is to be performed.

6.2 The term "about" used in claims 1-5,8, 19-23, 29-33, 39, 45 and 49 is vague and unclear and leaves the reader in doubt as to the meaning of the technical features to which it refers, thereby rendering the definition of the subject-matter of said claims unclear, Article 6 PCT.

6.3 The term "micronized" used in claims 18, 27, 44 and 47 is vague and unclear and leaves the reader in doubt as to the meaning of the technical features to which it refers, thereby rendering the definition of the subject-matter of said claims unclear, Article 6 PCT.

6.4 Claim 47 refers to a "process according to claim 28", although claim 28 is a product claim. Claim 47 is therefore not clear.